

ORIGINAL

Attorney Docket No. Le A 33 820

DT03 Rec'd PCT/PTO 15 NOV 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Haynes, et al.

Serial No.: 09/743,827

Group Art Unit: 1626

Filed: 07/31/01

Examiner: S.N. Wright

For: Antiparasitic Artemisinin Derivatives (endoperoxides)

**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

CERTIFICATION OF MAILING UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence and any papers referred to as attached are being deposited, on the date shown below, with the United States Postal Service, with sufficient postage, as first class mail in an envelope addressed to the Commissioner for Patents, Alexandria, VA 22313-1450.

Date: *NOV. 10, 2004*

Mariellen Chapdelaine
Signature of Person Certifying/Mariellen Chapdelaine

**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING
REJECTION OVER A PRIOR PATENT**

Sir:

The owner, BAYER AG, of 100% interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 6,649,647. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that said prior patent later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

The Commissioner is hereby authorized to charge the Terminal disclaimer fee under 37 CFR 1.20(d) to Deposit Account 13-3372. A duplicate of this sheet is attached.

Respectfully submitted,

Date: *10 November 2004*

Telephone: (203) 812-2786

Facsimile (203) 812-6459

Barbara A. Shimei
Barbara A. Shimei
Attorney of Record
Registration No.: 29, 862
Bayer Pharmaceuticals Corporation
400 Morgan Lane
West Haven, CT 06516-4175

ORIGINAL

PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
LeA 33 820

In re Application of:
Haynes et al.

Serial No.: 09/743,827

Filed: 7/31/01

For: Antiparasitic Artemisinin Derivatives
(endoperoxides)

Examiner: S.N.Wright

Group Art Unit: 1626

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this paper
(along with any paper referred
to as being attached or
enclosed) is being deposited
with the United States Postal
Service as first class mail,
postage prepaid, in an
envelope addressed to:
Commissioner for Patents, P.O.
Box 1450, Alexandria, VA
22313-1450, on this date: 10
November 2004

Mariellen Chapdelaine
Mariellen Chapdelaine

Sir:

REQUEST FOR EXTENSION OF TIME

Applicants hereby request that the time for responding to the Office Action of 10 May 2004 be extended for three (3) months so as to expire on 10 November 2004.

The Commissioner is hereby authorized to charge the fee under 37 CFR 1.17(a)(3) for a three-month extension of time, and any other fees under 37 CFR 1.16 and/or 1.17 required as a result of this petition, to Deposit Account No. 13-3372. A duplicate of this sheet is enclosed.

REMARKS

Claims 16, 23, and 28-34 are pending in this application.

Claims 16 and 29-34 have been rejected under the judicially-created doctrine of double patenting over claim 5 of USP 6,649,647. Claims 16 and 23 have been rejected under 35 USC 102(b). Claim 16 has been rejected under 35 USC 112, second paragraph. For the reasons set forth below, reconsideration is respectfully requested.

Rejection under the judicially-created doctrine of double-patenting

Claims 16 and 39-34 are rejected under the judicially created doctrine of double patenting over claim 5 of U.S. Patent No. 6,649,647, Hayes et al. since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In the instant claims, in formula (1), Y is defined to be –NR₁R₂ where R₁ and R₂ together with the interjacent nitrogen atom represent an optionally substituted nonaromatic heterocyclic group. Claim 5 of the '647 patent teaches variable "A" which corresponds to variable "Y" of the instant claims. In the '647 patent, A is defined to be –NR₃R₄ wherein R₃ and R₄ together with the interjacent nitrogen atom represent an optionally substituted heterocyclic group. Therefore, the subject matter of instant claims 16, and 29-34 is encompassed in claim 5 of the '647 patent. The '647 patent provides motivation to prepare the compounds in claims 16 and 29-34 through the species Examples in column 35, lines 33-38. Further motivation is provided in the '647 patent in column 10, lines 50-55, which states that "In a further preferred aspect, Y may represent a group –NR₃R₄ where . . . R₃ and R₄ together with the interjacent nitrogen atom represent a 5 to 10- membered heterocyclic group."

The present application and USP 6,649,647 were under a common obligation of assignment to The Hong Kong University of Science & Technology at the time both inventions were made. Subsequently The Hong Kong University of Science and Technology transferred title to Bayer AG, which has by contract transferred its rights to Bayer Business Services GmbH, which has in turn transferred its rights by contract to Bayer HealthCare AG. Assignment of title in the U.S. has not yet taken place between Bayer AG and Bayer HealthCare AG.

Enclosed is a terminal disclaimer of the present application over USP 6,649,647 by Bayer AG, the current owner of this application. Bayer Business Services GmbH and Bayer HealthCare AG are in accord with this terminal disclaimer.

Rejection under 35 USC 102(b):

Claims 16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1122806, Li et al. (STN International 1999:234337; RN 221890-88-6 and RN 221890-90-0, Abstract).

RN 221890-88-6 anticipates the instant compound when in the instant compounds, Y is $-NR_1R_2$ wherein R1 and R2 together with the interjacent nitrogen atom represent 9H-purin-6-amine.

RN 221890-90-0 anticipated the instant compound when, in the instant compounds, Y is $-NR_1R_2$ wherein R1 and R2 together with the interjacent nitrogen atom represent 1H-1,2,4-triazole-3-carboxamide.

The abstract in STN International discloses that the compound of Li et al. is useful in antitumor agents.

Claim 16 is directed to compounds of formula 1 in which Y is $-NR_1R_2$ where R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted nonaromatic heterocyclic group.

Claim 23 is directed to a pharmaceutical composition comprising a carrier and, as an active ingredient, a compound of the general formula 1 according to Claim 16.

9H-purin-6-amine and 1H-1,2,4-triazole-3-carboxamide represent aromatic heterocycles and accordingly do not anticipate the present claims.

Rejection under 35 USC 112, second paragraph:

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted non-aromatic heterocyclic group. However, it is unclear what substituents may appear on the heterocyclic group. For example, the elected species, Example 7, contains two oxo groups on the sulfur in the thiomorpholine ring. However, the term "oxo" does not appear in the list of substituents on page 11, lines 17-23. Clarification is requested regarding whether dioxothiomorpholine is the only compound intended to have oxo groups as substituents on the heterocyclic group.

Claim 28 is rejected for being dependent on claim 16.

The term "dioxothiomorpholino" is a synonym for "morpholinosulfonyl" but the compound of Example 7 is not considered a substituted thiomorpholino. Oxidized sulfur is in general not considered a "substituted" sulfur, but a separate chemical entity, e.g. a sulfoxide, sulfur dioxide, sulfonyl, sulfonic acid, etc. The nomenclature allows organic compounds containing sulfur to be referred to as "oxo-thio" and the like but this does not imply a "substituted" sulfur. The synonym "morpholinosulphonyl" shows this clearly. See also p. 10 lines 26-27 where morpholinosulphonyl as well as thiomorpholinyl are listed as different heterocyclyl species suitable for use in the present invention. As the dioxothiosulphonyl/morpholinosulphonyl is not considered substituted, "oxo" is not listed as a substituent on page 11, lines 17-23. Therefore it is clear to a person skilled in the art that the oxo moiety is an integral part of the dioxothiosulphonyl/morpholinosulfonyl heterocycle and is not intended as a substituent on other heterocycles.

The Commissioner is hereby authorized to charge any fees required as a result of this Amendment to Deposit Account 13-3372. A duplicate of this sheet is enclosed.

For the foregoing reasons it is believed this application is now in condition for allowance and such action is earnestly solicited.

Respectfully submitted,



Barbara A. Shimei

Reg. No. 29,862

Attorney for Applicants

Bayer Pharmaceuticals Corporation

400 Morgan Lane

West Haven, CT 06516

Phone: (203) 812-2786

Fax: (203) 812-6459